

FLORIAN KERN ET AL.  
USSN 09/600,564  
REPLY TO OFFICE ACTION DATED MAY 4, 2004  
AMENDMENT OF APRIL 4, 2005

CONDITIONAL PETITION FOR EXTENSION OF TIME

If entry and consideration of the amendments above requires an extension of time, Applicants respectfully request that this be considered a petition therefor. The Commissioner is authorized to charge any fee(s) due in this connection to Deposit Account No. 14-1263.

ADDITIONAL FEE

Please charge any insufficiency of fees, or credit any excess, to Deposit Account No. 14-1263.

REMARKS

Applicants respectfully request reconsideration and allowance of this application in view of the amendments above and the following comments.

New claim 27 is presented. New claim 27 finds clear support in the original application as filed. Applicants do not believe that new claim 27 introduces any new matter. An early notice to that effect is earnestly solicited.

The sole substantive issue for consideration is the rejection of claims 14-21 under 35 USC § 102(b) as being anticipated by Woitas et al. ("Woitas"), *J. Immunol.*, 159: 1012-1018 (1997). In response, Applicants would remind the Examiner that anticipation requires that each

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and every element as set forth in the claim must be found, either expressly or inherently described, in a single prior art reference, and, further, the absence in the prior art reference of even a single one of the claim elements is sufficient to negate anticipation. *In re Robertson*, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999). The rejected claims require that “the *incubation time* of the suspension containing *T cells with the protein fragment or fragments* is sufficiently short so that selection and proliferation accompanied *by the specific elimination of particular T cells do not occur.*” *Woitas* does not teach such a short incubation period. Consequently, *Woitas* cannot anticipate the rejected claims.

In support of their position, Applicants have simultaneously filed three declarations pursuant to 37 CFR § 1.132. These are:

- 1) The Declaration of Dr. Rainer Woitas, the principal investigator of the *Woitas* reference;
- 2) The Declaration of Dr. Florian Kern, one of the co-inventors on the present application; and
- 3) The Declaration of Dr. Holden Maecker, a Group Manager at BD Biosciences in San Jose, CA.

The Examiner took the position that *Woitas* taught both long incubation times of up to 40 hours and short incubation times such as 30 minutes. See the first paragraph on page 4 of the

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Office Action.

At the outset, Applicants stress that Woitas nowhere teaches an incubation period of “*up to 40 hours*.” Rather, Woitas teaches an incubation period of “40 hours” period. If the Examiner maintains this rejection and disagrees, Applicants respectfully requests that the Examiner point out where in Woitas there is a teaching of “up to 40 hours” as opposed to “40 hours.”

Next, as discussed in the accompanying declarations the long incubation time of 40 hours is too long to avoid the specific elimination of particular T cells. See numbered paragraph 6 in the Kern Declaration:

“This period is sufficiently long to result in stimulation-induced apoptosis and cell death. This potential loss of healthy induced cells is likely to impair the accurate measurement of a given peptide’s stimulatory properties in terms of the number of induced T-lymphocytes.”

See also numbered paragraph 6 in the Maecker Declaration, which is to the same effect. Consequently, this incubation period does not satisfy the claim limitation that “the *incubation time of* the suspension containing T cells with the protein fragment or fragments is sufficiently short so that selection and proliferation accompanied *by the specific elimination of particular T cells do not occur.*”

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On the other hand, as also discussed in these declarations, the incubation time of 30 minutes does not relate to T cell stimulation at all. The 30 minute incubation period involved incubation of fixed and permeabilized cells *with antibodies* for the purpose of immunolabeling, which could not possibly have any effect on the level of peptide-induced stimulation. See numbered paragraph 5 in the Woitas Declaration; numbered paragraph 5 in the Kern Declaration; and numbered paragraph 5 in the Maecker Declaration. As this incubation period does not involve an incubation of the T cells with the one or more protein fragments, this limitation does not satisfy the rejected claim limitations that “the *incubation time of the suspension containing T cells with the protein fragment or fragments* is sufficiently short so that selection and proliferation accompanied by the specific elimination of particular T cells do not occur.”

In view of the foregoing, Applicants submit that the Examiner would be fully justified to reconsider and withdraw this rejection. An early notice that this rejection has been reconsidered and withdrawn is earnestly solicited.

Applicants believe that the foregoing constitutes a bona fide response to all outstanding objections and rejections.

Applicants also believe that this application is in condition for immediate allowance. However, should any issue(s) of a minor nature remain, the Examiner is respectfully requested to telephone the undersigned at telephone number (212) 808-0700 so that the issue(s) might be

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USSN 09/600,564  
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AMENDMENT OF APRIL 4, 2005

promptly resolved.

Early and favorable action is earnestly solicited.

Respectfully submitted,

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By

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CERTIFICATE OF FACSIMILE TRANSMISSION

I hereby certify that the foregoing Amendment under 37 CFR § 1.111 (15 pages total) is being facsimile transmitted to the United States Patent and Trademark Office on the date indicated below:

Date: April 4, 2005

By:

Kurt G. Briscoe